REMARKS

I. Preliminary Remarks

Claim 1 has been amended to more clearly recite that the drug is connected through the central Phe of the listed group of tripeptides. The cancelled language ("not terminal proteolytic enzyme cleavable amino acid") was an artifact of the original claims which contemplated both tripeptides and tetrapeptides but is not necessary for a clear understanding of the claims.

Claims 7, 21 and 22 have been canceled to expedite allowance of the remaining claims.

II. Outstanding Rejections

Claims 1-2, 6, 11, 16, 18-20 stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

Claims 1-2, 6, 11, 16, 18, 20 and 21 stand rejected under 35 U.S.C. §112 (first paragraph) as failing to comply with the written description requirement and as introducing new matter when claim 1 is interpreted to mean that "the conjugation of the drug is not through the terminal proteolytic enzyme cleavable amino acid moiety."

Claims 7 (and sic 8) stand rejected under 35 U.S.C. §112 (first paragraph) as failing to comply with the written description requirement.

Claims 1-2, 6, 16, 18 and 20 also stand rejected under 35 U.S.C. §102(b) as being anticipated by Barbieri, US 3,814,746.

Claims 7, 21 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lewensohn et al., WO 01/96367.

III. Patentability Arguments

A. The rejections of claims 1-2, 6, 11, 16, 18-20 under 35 U.S.C. §112 (second paragraph) as being indefinite should be withdrawn.

The rejections of claims 1-2, 6, 11, 16 and 18-20 under 35 U.S.C. §112 (second paragraph) as being indefinite should be withdrawn in light of the amendment of claim 1 to specify that the drug is connected to the central Phe of the tripeptide.

B. The rejections of claims 1-2, 6, 11, 16, 18 and 20 under 35 U.S.C. §112 (first paragraph) as failing to comply with the written description requirement should be withdrawn.

The rejections of claims 1-2, 6, 11, 16, 18 and 20 under 35 U.S.C. §112 (first paragraph) should be withdrawn in light of the clarifying amendment of claim 1 because the drug is connected through the central amino acid (Phe) of the tripeptide such as illustrated in Example 2 of the disclosure. Moreover, there is no affirmative teaching in the application disclosing a terminal coupling of the drug. Thus, responding to the Examiner's inquiry, claim 1 does not mean that the conjugation of the drug is not through the terminal proteolytic enzyme cleavable amino acid moiety.

It is believed that the current amendment of claim 1 resolves any previous issue of new matter but by way of explanation it is submitted that the previous amendment did not do so either. As originally filed, the application encompassed two embodiments. In one embodiment, the peptide comprised an amino acid substituted with a pharmacologically reactive group, in a second embodiment, a (non-amino acid or peptide) drug, known per se to be effective was coupled to a peptide.

In the first embodiment, either the whole peptide has to be considered to be the drug or (in the case of a pharmacologically active amino acid forming part of the peptide) as incorporates the drug. In the second embodiment, the peptide coupled to a drug results in a pro-drug. At present, only the second embodiment (the pro-drug) embodiment is prosecuted.

With regard to the alleged new matter the attention of the Examiner is directed to the examples and to the following aspects of the disclosure as originally filed:

"...the peptide of the present invention comprise at least one proteolytic enzymes cleavable site being or carrying the drug..." (pg. 4, lines 1-3);

"...comprise as the (preferably not terminal) cleavable group..." (pg. 4, lines 26-27)

and pg. 13, original claim 3 and page 13, original claim 7 defining the proteolytic enzyme cleavable amino acid moiety as substituted with a substituent sufficiently reactive to be useful in drug coupling reactions. This statement combined with the disclosure of originally filed claim 3 provided support for the claims. In any event, it is submitted that claim 1 as currently amended is both clear and is supported by the original disclosure.

For these reasons, the rejections of claims 1-2, 6, 11, 16, 18 and 20 under 35 U.S.C. §112 (first paragraph) for lack of written description should be withdrawn.

C. The rejections of claim 7 (and sic 8) under 35 U.S.C. §112 (first paragraph) as failing to comply with the written description requirement may be withdrawn in light of the cancellation of those claims.

D. The rejections of Claims 1-2, 6, 16, 18 and 20 also stand rejected under 35 U.S.C. §102(b) as being anticipated by Barbieri US 3,814,746 should be withdrawn.

The anticipation rejections under Barbieri, US 3,814,746 should be withdrawn because in contrast to the present invention, where the drug is coupled to a not terminal amino acid (the central Phe), the tetracycline of US 3,814,746 is bound to the N-terminus of the peptide!

The claim limitation that the linkage be through the central peptide ensures that neither the N-terminus nor the C-terminus of the peptide are blocked or sterically hindered by the drug. By coupling to the not terminal amino acid as, e.g., disclosed in Example 2, both the N-terminal as well as the C-terminal remain unchanged and thus the amino and the carboxy function retain their ability to interact with the blood cells that are acting as transport vehicle. This element of the claims is nowhere disclosed in Barbieri and accordingly, the anticipation rejection should be withdrawn.

E. The rejections of claims 7, 21 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lewensohn et al. WO 01/96367 may be withdrawn in light of the cancellation of those claims.

CONCLUSION

For the foregoing reasons, it is submitted that each of claims 1, 2, 6, 7, 11, 16, 18 and 20 should now be allowed. Should the Examiner wish to discuss any issues of form or substance, he is invited to contact the undersigned attorney at the number below.

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Respectfully submitted,

By _____

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